IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Manabu NAKATANI, et al.	:	
	:	Examiner: Caralynne E. Helm
Serial No.: 10/664,725	:	Group Art Unit: 1615
Filed: September 18, 2003	:	

For: SOLID TELMISARTAN PHARMACEUTICAL FORMULATIONS

BRIEF ON APPEAL UNDER 37 C.F.R. §41.37

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal from the decision of the Examiner finally rejecting claims 1-3 and 6-15 of the above-identified application. A Notice of Appeal was filed on January 13, 2010.

(i) REAL PARTY IN INTEREST

The application is assigned of record to Boehringer Ingelheim International GmbH, who is the real party in interest herein.

(ii) RELATED APPEALS AND INTERFERENCES

Appellants, their legal representative and the assignee are not aware of any related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

(iii) STATUS OF THE CLAIMS

Claims rejected:	Claims 1-3 and 6-15.
Claims allowed:	(none)
Claims canceled:	Claims 4 and 5.
Claims withdrawn:	(none)

Claims on Appeal: Claims 1-3 and 6-15 (Copy of claims on appeal in attached Appendix).

(iv) STATUS OF AMENDMENTS

No amendments after the Final Rejection have been proposed by Appellants.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention (independent claim 1) is directed to a pharmaceutical composition comprising 3 wt.% to 50 wt.% telmisartan dispersed in a dissolving matrix (see, e.g., page 1, lines 9-10; page 2, lines 10-14; and page 3, lines 13-16; of the specification). The dissolving matrix comprises: (a) a basic agent in a molar ratio of basic agent:telmisartan of 1:1 to 10:1; (b) about 1 wt.% to about 20 wt.% of polyoxamers [sic: poloxamers] having an average molecular weight of about 2000 to 12000; (c) 25 wt.% to 70 wt.% of a water-soluble diluent; and (d) 0 wt.% to 20 wt.% of one or more additional excipients and/or adjuvants, wherein the sum of all components is 100% (see, e.g., page 3, lines 17-27; and page 4, lines 6-16; of the specification).

A typographical error in claim 1, on appeal, is noted above. This error will be corrected post-appeal.

Appellants' invention (dependent claim 13, separately rejected and argued) is directed to a bilayer pharmaceutical tablet comprising: (a) a first telmisartan-containing tablet layer comprising the pharmaceutical composition of one of claims 1 to 9; and (b) a second tablet layer containing a diuretic in a disintegrating tablet matrix (see, e.g., page 11, lines 20-23, of the specification).

Appellants' invention (dependent claim 14, separately rejected and argued) is directed to a process for preparing the pharmaceutical composition of claim 1 using a fluid-bed granulation process, comprising:

(i) preparing a granulation liquid as an aqueous solution by dissolving 3 wt.% to 50 wt.% of telmisartan together with the following components in water or in a mixture solution of ethanol and water:

(a) a basic agent in a molar ratio of basic agent:telmisartan of 1:1 to 10:1, and

(b) polyoxamers having an average molecular weight of about 2000 to 12000

in an amount of about 1 wt.% to about 20 wt.%;

(ii) placing 25 wt.% to 70 wt.% of a water-soluble diluent in a fluid-bed granulator, optionally together with 10 wt.% to 20 wt.% of a dry binder, including a premix-step;

(iii) carrying out the fluid-bed granulation using the granulation liquid for spraying on the components placed in the granulator;

(iv) drying the granulation thus obtained and, optionally, screening the granulate obtained;

(v) optionally blending the granulate with one or more additional excipients and/or adjuvants; and

(vi) optionally milling the granulate thus obtained in order to produce a powdery composition of defined particle size distribution;

wherein all percentage amounts given are related to the final composition to be prepared (see, e.g., page 12, line 23, to page 13, line 19, of the specification).

Appellants' invention (dependent claim 15, separately rejected and argued) is directed to a process for preparing the pharmaceutical composition of claim 1 using a spray drying process, comprising:

(i) preparing an aqueous spray-solution by dissolving 3 wt.% to 50 wt.% of telmisartan together with the following components in water or mixture solution of ethanol and water:

(a) a basic agent in a molar ratio of basic agent:telmisartan of 1:1 to 10:1, and

(b) polyoxamers having an average molecular weight of about 2000 to 12000

in an amount of about 1 wt.% to 20 wt.%;

(ii) spray-drying the aqueous spray-solution to obtain a spray-dried granulate;

(iii) mixing the spray-dried granulate with 25 wt.% to 70 wt.% of a water-soluble diluent to obtain a premix;

(iv) optionally mixing the premix with a lubricant;

(v) optionally adding additional excipients and/or adjuvants in any of steps (i) to (iv),

wherein all percentage amounts given are related to the final composition to be prepared (see, e.g., page 14, lines 6-27, of the specification).

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following outstanding grounds of rejection are requested to be reviewed on appeal. For each ground, any separate consideration of the claims subject to that rejection is indicated.

1. The rejection of claims 1 to 3 and 6 to 12 as allegedly obvious under 35 U.S.C. § 103(a) over Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744).

2. The rejection of claims 1 to 3, 6 to 9, and 13 as allegedly obvious under 35 U.S.C. § 103(a) over McGill (Clinical Therapeutics 2001) in view of Raghunathan (U.S. Patent No. 4,522,818) as well as Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744).

2a. Claims 1 to 3 and 6 to 9, on appeal, are grouped together.

2b. Claim 13, on appeal, is separately grouped for the reasons given in the argument.

3. The rejection of claims 1 and 14 as allegedly obvious under 35 U.S.C. § 103(a) over Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744) and further in view of Curatollo (U.S. Patent No. 6,068,859), Schnieder (U.S. Patent No. 6,358,986), and as evidenced by Gennaro (*Remington Pharmaceutical Sciences*, 19th ed. 1995, p. 1625).

3a. and 3b. Claims 1 and 14, on appeal, are grouped separately from one another for the reasons given in the argument.

4. The rejection of claims 1 and 15 as allegedly obvious under 35 U.S.C. § 103(a) over Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744) and further in view of Schnieder (U.S. Patent No. 6,358,986).

4a. and 4b. Claims 1 and 15, on appeal, are grouped separately from one another for the reasons given in the argument.

(vii) ARGUMENT

1. Claims 1 to 3 and 6 to 12, on appeal, are not obvious to one of ordinary skill in the art over Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744); thus, the rejection under 35 U.S.C. § 103(a) should be reversed.

Gaviraghi discloses compositions comprising the two actives lacidipine and telmisartan used for treating cardiovascular disorders, see, e.g., page 1, lines 26-29. The characterizing feature of the Gaviraghi invention is the alleged synergistic effect in treating hypertension by using this combination of actives. The main body of the Gaviraghi reference does not give much detail about the nature of specific formulations with the two actives. However, Gaviraghi does give Examples of specific tablets at pages 12-16. The Final Office action points to Example 2 of Gaviraghi but Example 2 is a bilayer tablet and it cannot be determined from the Example which components are in which layer. Example 1 of Gaviraghi, however, discloses a homogeneous tablet having a very similar combination of components and appellants will refer to this formulation below.

The composition of Example 1 contains the two actives lacidipine and telmisartan (40mg), monohydrate lactose, sodium hydroxide (a basic agent), meglumine (also a basic agent), povidone (disclosed on page 8, line 2, to be a binder), sorbitol and magnesium stearate.

The Gaviraghi composition fails to meet the element of claim 1, on appeal, of having "about 1 wt.% to about 20 wt.% of polyoxamers [sic: poloxamers] having an average molecular weight of about 2000 to 12000." There is no poloxamer component referred to in this Example or anywhere else in Gaviraghi. Poloxamers are triblock copolymers having a central hydrophobic chain of polyoxypropylene flanked by two hydrophilic chains of polyoxyethylene. Pluronic is a tradename for poloxamers.

The Gaviraghi composition also fails to meet at least one of the following two elements of claim 1, on appeal, i.e., "25 wt.% to 70 wt.% of a water-soluble diluent" and "0 wt.% to 20 wt.% of one or more additional excipients and/or adjuvants." The sorbitol component is a water-soluble diluent. If the lactose monohydrate is also considered a water-soluble diluent component, then the total amount of water-soluble diluent is in excess of 70 wt.% (39% lactose monohydrate and 37% sorbitol). If the lactose monohydrate is not considered a water-soluble diluent component, then it is an additional excipient and/or

adjuvant and is in excess of 20 wt.%. Thus, under either interpretation, Gaviraghi also fails to meet one of these other claim elements.

Doi teaches compositions combining an NK-1 receptor antagonist, and NK-2 receptor antagonist and/or an anticholinergic. It is particularly directed to compositions where the NK-1 receptor antagonist is a compound of the formula (I). The compositions are taught to treat a varied list of conditions related to tachykinin receptor antagonist activity, particularly urinary incontinence. See, e.g, page 1, paras. 0002, 0009 and 0010, and pages 20-21, para. 0395. Doi discloses a wide variety of possible additional additives to its compositions depending on the various forms of administration chosen; see, e.g., pages 21-26, paras. 0398-0480.

It is alleged in the Final Office action (page 3, third paragraph) that Doi teaches that polyvinylpyrrolidone (povidone) and Pluronic® F68 (poloxamer 188) were known as binders for solid pharmaceutical dosage forms (see, page 23, para. 0448, of Doi). Appellants respectfully submit that Doi only teaches that polyvinylpyrrolidone (povidone) and Pluronic® F68 (poloxamer 188) were possible selections of binders – among others – for particular core-based pharmaceutical compositions specific to its particular combination of NK-1 receptor antagonist, and NK-2 receptor antagonist and/or an anticholinergic used to treat conditions related to tachykinin receptor antagonist activity. Doi does not teach that those components are useful as binders for any pharmaceutical composition. Further, Doi indicates a preference for polyvinylpyrrolidone (povidone) for its compositions and no preference to Pluronic® F68 (poloxamer 188).

Frisbee teaches an active agent delivery system for providing rapid release of agents that are not normally readily soluble. The system is achieved by thermoforming the active along with a solubilizing agent prior to forming the dosage form; see, e.g., page 1, lines 5-10. Frisbee teaches that poloxamers, particularly poloxamer 188, are suitable solubilizing agents for this system; see, e.g., page 5, lines 20-31. Frisbee does not teach the poloxamers are generally useful as excipients for any pharmaceutical compositions, just its specific application. Further, Frisbee does not teach the poloxamers as binders.

It is alleged in the Final Office action (paragraph bridging pages 3-4) that the cited references establish polyvinylpyrrolidone (povidone) and Pluronic® F68 (poloxamer 188) as functional equivalents and that it would have been obvious to exchange the Pluronic® F68 (poloxamer 188) taught by Doi for the polyvinylpyrrolidone (povidone) in the Gaviraghi compositions.

Appellants disagree that Doi teaches that polyvinylpyrrolidone (povidone) and Pluronic® F68 (poloxamer 188) are functional equivalents. Doi teaches that they could both be used as binders for a particular application related to a particular administration form for a particular combination of active agents. Even in this sense, it does not teach them to be equivalent because it indicates that polyvinylpyrrolidone (povidone) is preferred, presumably meaning it has some different and advantageous property compared to Pluronic® F68 (poloxamer 188). However, even if Doi does teach them to be equivalent for the specific use set forth in Doi, this would not suggest to one of ordinary skill in the art that they would be equivalent and interchangeable in the Gaviraghi compositions. The Doi compositions relate to distinct compounds from those in the Gaviraghi compositions and the compositions have distinct properties and distinct uses. The reference teachings do not provide one of ordinary skill in the art a reasonable expectation that the binders indicated for the specific use of Doi would have the same or similar use in the Gaviraghi compositions. Further, the disclosure in Doi relied on regarding the polyvinylpyrrolidone (povidone) and Pluronic® F68 (poloxamer 188) binders only applies to a very specific embodiment of Doi, i.e., compositions with the active in a solid core which is coated by a film-forming agent. In the other embodiments of Doi, the indication of useful binders or carriers includes polyvinylpyrrolidone (povidone) but not Pluronic® F68 (poloxamer 188) or other poloxamers; see, e.g., page 21, para. 0402; and, page 25, para. 0471. Thus, further indicating that they are not equivalent. For this additional reason, Doi does not provide a reasonable expectation that the binders indicated for the specific embodiment of Doi would have the same or similar use in the Gaviraghi compositions, which are not indicated to be in the form of a solid core which is coated by a film-forming agent.

Frisbee does not provide any reasons for one of ordinary skill in the art to exchange the Pluronic® F68 (poloxamer 188) taught by Doi for the polyvinylpyrrolidone (povidone) in the Gaviraghi compositions. Frisbee does not even indicate that the poloxamers used in its invention are binders and makes no connection between poloxamers and polyvinylpyrrolidone (povidone). Frisbee merely teaches the molecular weight of poloxamer 188, which appellants do not dispute.

For all of the above reasons, appellants submit that the combined teachings of the cited references fail to provide the required "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (KSR International Co. v. Teleflex Inc., 550 U.S. _, 82 USPQ2d 1385, at 1396 (2007)), i.e., a reason to exchange the

polyvinylpyrrolidone (povidone) in Gaviraghi with Pluronic® F68 (poloxamer 188), or other poloxamer.

Furthermore, even if the polyvinylpyrrolidone (povidone) of Gaviraghi was substituted by poloxamer 188, the Gaviraghi composition would still be distinct from the claimed compositions. Such a modified composition would still fail to meet either the "25 wt.% to 70 wt.% of a water-soluble diluent" element of claim 1, on appeal, or the "0 wt.% to 20 wt.% of one or more additional excipients and/or adjuvants" element of claim 1, on appeal. As explained above, in such a modified composition, if the lactose monohydrate is also considered a water-soluble diluent component together with the sorbitol, then the total amount of water-soluble diluent is in excess of 70 wt.% (39% lactose monohydrate and 37% sorbitol). And, if the lactose monohydrate is not considered a water-soluble diluent component, then it is an additional excipient and/or adjuvant and is in excess of 20 wt.%. For this additional reason, the combined teachings of the cited references fail to provide the "articulated reasoning with some rational underpinning" to support obviousness.

For all of the above reasons, it is urged that the combined teachings of Gaviraghi, Doi and Frisbee fail to render the claimed invention obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. §103 should be reversed.

2a. Claims 1 to 3 and 6 to 9 are not obvious to one of ordinary skill in the art over McGill (Clinical Therapeutics 2001) in view of Raghunathan (U.S. Patent No. 4,522,818) as well as Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744); thus, the rejection under 35 U.S.C. § 103(a) should be reversed.

The statement of this rejection in the Final Office action addresses only claim 13, on appeal. No reasons additional those already addressed in Issue 1 above were provided for rejecting claims 1 to 3 and 6 to 9, on appeal. The additional McGill and Raghunathan references were only cited regarding the additional diuretic component aspect, which is not a feature of any of claims 1 to 3 and 6 to 9, on appeal. Thus, appellants' arguments in Issue 1 above fully address this ground of rejection as applied to claims 1 to 3 and 6 to 9, on appeal, and are incorporated herein by reference. The rejection as to these claims should be reversed for these reasons.

2b. Claim 13 is not obvious to one of ordinary skill in the art over McGill (Clinical

Therapeutics 2001) in view of Raghunathan (U.S. Patent No. 4,522,818) as well as Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744); thus, the rejection under 35 U.S.C. § 103(a) should be reversed.

The Gaviraghi, Doi and Frisbee references are discussed above in Issue 1 and that discussion is incorporated by reference herein. The rejection of claim 13, on appeal, relies on the premise that Gaviraghi, Doi and Frisbee teach or suggest the compositions of claim 1, on appeal. For the reasons stated in Issue 1, the combined teachings of Gaviraghi, Doi and Frisbee do not teach or suggest the compositions of claim 1, on appeal. Thus, the premise forming a necessary basis of the rejection is not met and the rejection should be reversed at least for this reason.

The McGill and Raghunathan references provide no teachings which would suggest modifying Gaviraghi to provide a telmisartan composition meeting the elements of instant claim 1, on appeal. Since the combined teachings of the five cited references fail to teach or suggest the telmisartan composition according to claim 1, on appeal, the combined teachings cannot suggest the bi-layer tablet of claim 13 which contains the telmisartan composition according to claim 1, on appeal.

For all of the above reasons, it is urged that the combined teachings of McGill, Raghunathan, Gaviraghi, Doi and Frisbee fail to render the invention of claim 13, on appeal, obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. §103 should be reversed.

3a. Claim 1 is not obvious to one of ordinary skill in the art over Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744) and further in view of Curatollo (U.S. Patent No. 6,068,859), Schnieder (U.S. Patent No. 6,358,986), and as evidenced by Gennaro (*Remington Pharmaceutical Sciences*, 19th ed. 1995, p. 1625); thus, the rejection under 35 U.S.C. § 103(a) should be reversed.

The statement of this rejection in the Final Office action addresses only claim 14, on appeal. No reasons additional those already addressed in Issue 1 above were provided for rejecting claim 1, on appeal. The additional Curatollo, Schneider and Gennaro references were only cited regarding the methods of preparing the compositions which is not a feature of claim 1, on appeal. Thus, appellants' arguments in Issue 1 above fully address this ground of rejection as applied to claim 1, on appeal, and are incorporated herein by reference. The

rejection as to this claim should be reversed for these reasons.

3b. Claim 14 is not obvious to one of ordinary skill in the art over Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744) and further in view of Curatollo (U.S. Patent No. 6,068,859), Schnieder (U.S. Patent No. 6,358,986), and as evidenced by Gennaro (*Remington Pharmaceutical Sciences*, 19th ed. 1995, p. 1625); thus, the rejection under 35 U.S.C. § 103(a) should be reversed.

The Gaviraghi, Doi and Frisbee references are discussed above in Issue 1 and that discussion is incorporated by reference herein. The rejection of claim 14, on appeal, relies on the premise that Gaviraghi, Doi and Frisbee teach or suggest the compositions of claim 1, on appeal. For the reasons stated in Issue 1, the combined teachings of Gaviraghi, Doi and Frisbee do not teach or suggest the compositions of claim 1, on appeal. Thus, the premise forming a necessary basis of the rejection is not met and the rejection should be reversed at least for this reason.

Furthermore, the methods taught in Curatollo, Schnieder and Gennaro do not relate to telmisartan or related compositions. There are no teachings in Curatollo, Schnieder or Gennaro, or their combined teachings, to suggest modifying the compositions of Gaviraghi in a way to arrive at the claimed compositions. Further, since Curatollo, Schnieder and Gennaro do not relate to telmisartan or related compositions, the steps taught in these references do not suggest the specific steps of the claimed invention which would provide the specific combination of components necessary to meet the elements of the claims on appeal. Even if the references taught that the steps of claim 14, on appeal, were generally known methods for preparing pharmaceutical compositions (which appellants do not admit), such teachings would not render the claimed invention obvious to one of ordinary skill in the art because there would be no motivation for one of ordinary skill in the art to adapt such general steps specifically for preparing a composition according to claim 1, on appeal. See, e.g., In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996), holding that the fact that the general scientific principles behind the types of process steps were generally known does not render the process obvious if the references do not provide a reason for one of ordinary skill in the art to apply those general scientific principles to the specific process of preparing the specific product claimed. In the instant case, the claimed product is not rendered obvious by the cited prior art, thus, there is no reason for one of ordinary skill in the art to apply any generally known

process steps to a process specific to preparing the product.

For all of the above reasons, it is urged that the combined teachings of Gaviraghi, Doi, Frisbee, Curatollo, Schnieder and Gennaro fail to render the invention of claim 14, on appeal, obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. §103 should be reversed.

4a. Claim 1 is not obvious to one of ordinary skill in the art over Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744) and further in view of Schnieder (U.S. Patent No. 6,358,986); thus, the rejection under 35 U.S.C. § 103(a) should be reversed.

The statement of this rejection in the Final Office action addresses only claim 15, on appeal. No reasons additional those already addressed in Issue 1 above were provided for rejecting claim 1, on appeal. The additional Schneider reference was only cited regarding the methods of preparing the compositions which is not a feature of claim 1, on appeal. Thus, appellants' arguments in Issue 1 above fully address this ground of rejection as applied to claim 1, on appeal, and are incorporated herein by reference. The rejection as to this claim should be reversed for these reasons.

4b. Claim 15 is not obvious to one of ordinary skill in the art over Gaviraghi (WO 00/27397) in view of Doi (U.S. Patent Publication No. 2004/0058914) and as evidenced by Frisbee (WO 99/17744) and further in view of Schnieder (U.S. Patent No. 6,358,986); thus, the rejection under 35 U.S.C. § 103(a) should be reversed.

The Gaviraghi, Doi and Frisbee references are discussed above in Issue 1 and that discussion is incorporated by reference herein. The rejection of claim 15, on appeal, relies on the premise that Gaviraghi, Doi and Frisbee teach or suggest the compositions of claim 1, on appeal. For the reasons stated in Issue 1, the combined teachings of Gaviraghi, Doi and Frisbee do not teach or suggest the compositions of claim 1, on appeal. Thus, the premise forming a necessary basis of the rejection is not met and the rejection should be reversed at least for this reason.

Furthermore, the methods taught in Curatollo, Schnieder and Gennaro do not relate to telmisartan or related compositions. There are no teachings in Curatollo, Schnieder or Gennaro, or their combined teachings, to suggest modifying the compositions of Gaviraghi in a way to arrive at the claimed compositions. Further, since Curatollo, Schnieder and Gennaro

do not relate to telmisartan or related compositions, the steps taught in these references do not suggest the specific steps of the claimed invention which would provide the specific combination of components necessary to meet the elements of the claims on appeal. Even if the references taught that the steps of claim 15, on appeal, were generally known methods for preparing pharmaceutical compositions (which appellants do not admit), such teachings would not render the claimed invention obvious to one of ordinary skill in the art because there would be no motivation for one of ordinary skill in the art to adapt such general steps specifically for preparing a composition according to claim 1, on appeal. See, e.g., In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996), holding that the fact that the general scientific principles behind the types of process steps were generally known does not render the process obvious if the references do not provide a reason for one of ordinary skill in the art to apply those general scientific principles to the specific process of preparing the specific product claimed. In the instant case, the claimed product is not rendered obvious by the cited prior art, thus, there is no reason for one of ordinary skill in the art to apply any generally known process steps to a process specific to preparing the product.

For all of the above reasons, it is urged that the combined teachings of Gaviraghi, Doi, Frisbee and Schnieder fail to render the invention of claim 15, on appeal, obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. §103 should be reversed.

For all of the above reasons, it is urged that the decision of the Examiner rejecting claims 1-3 and 6-15, on appeal, is in error and should be reversed.

Respectfully submitted,

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(viii) CLAIMS APPENDIX

1. A pharmaceutical composition comprising 3 wt.% to 50 wt.% telmisartan dispersed in a dissolving matrix comprising:

(a) a basic agent in a molar ratio of basic agent:telmisartan of 1:1 to 10:1;

(b) about 1 wt.% to about 20 wt.% of polyoxamers having an average molecular weight of about 2000 to 12000;

(c) 25 wt.% to 70 wt.% of a water-soluble diluent; and

(d) 0 wt.% to 20 wt.% of one or more additional excipients and/or adjuvants,

wherein the sum of all components is 100%.

2. The pharmaceutical composition of claim 1, wherein the basic agent is a metal hydroxide or a basic amino acid.

3. The pharmaceutical composition of claim 1, wherein the basic agent is NaOH, KOH, $NaHCO_3$, $KHCO_3$, Na_2CO_3, K_2CO_3, Na_2HPO_4, K_2HPO_4, arginine, or meglumine.

6. The pharmaceutical composition of claim 1, wherein the poloxamers are poloxamer 182LF, poloxamer 331, or poloxamer 188.

7. The pharmaceutical composition of claim 1, wherein the water-soluble diluent is selected from carbohydrates, oligosaccharides, and sugar alcohols.

8. The pharmaceutical composition of claim 1, wherein the water-soluble diluent is glucose, sucrose, erythritol, sorbitol, mannitol, dulcitol, ribitol, or xylitol.

9. The pharmaceutical composition of claim 1, wherein the additional excipients and/or adjuvants are selected from binders, carriers, lubricants, flow control agents, crystallization retarders, solubilizers, and coloring agents.

10. The pharmaceutical composition of claim 1 in the form of a capsule or a tablet.

11. The pharmaceutical composition of claim 1 or claim 10, comprising a dosage unit of 10 mg to 160 mg of telmisartan.

12. The pharmaceutical composition of claim 10, comprising a dosage unit of 10 mg to 160 mg of telmisartan.

13. A bilayer pharmaceutical tablet comprising:

(a) a first telmisartan-containing tablet layer comprising the pharmaceutical composition of one of claims 1 to 9; and

(b) a second tablet layer containing a diuretic in a disintegrating tablet matrix.

14. A process for preparing the pharmaceutical composition of claim 1 using a fluid-bed granulation process, comprising:

(i) preparing a granulation liquid as an aqueous solution by dissolving 3 wt.% to 50 wt.% of telmisartan together with the following components in water or in a mixture solution of ethanol and water:

  (a) a basic agent in a molar ratio of basic agent:telmisartan of 1:1 to 10:1, and

  (b) polyoxamers having an average molecular weight of about 2000 to 12000 in an amount of about 1 wt.% to about 20 wt.%;

(ii) placing 25 wt.% to 70 wt.% of a water-soluble diluent in a fluid-bed granulator, optionally together with 10 wt.% to 20 wt.% of a dry binder, including a premix-step;

(iii) carrying out the fluid-bed granulation using the granulation liquid for spraying on the components placed in the granulator;

(iv) drying the granulation thus obtained and, optionally, screening the granulate obtained;

(v) optionally blending the granulate with one or more additional excipients and/or adjuvants; and

(vi) optionally milling the granulate thus obtained in order to produce a powdery composition of defined particle size distribution;

wherein all percentage amounts given are related to the final composition to be prepared.

15. A process for preparing the pharmaceutical composition of claim 1 using a spray drying process, comprising:

(i) preparing an aqueous spray-solution by dissolving 3 wt.% to 50 wt.% of telmisartan together with the following components in water or mixture solution of ethanol and water:

(a) a basic agent in a molar ratio of basic agent:telmisartan of 1:1 to 10:1, and

(b) polyoxamers having an average molecular weight of about 2000 to 12000 in an amount of about 1 wt.% to 20 wt.%;

(ii) spray-drying the aqueous spray-solution to obtain a spray-dried granulate;

(iii) mixing the spray-dried granulate with 25 wt.% to 70 wt.% of a water-soluble diluent to obtain a premix;

(iv) optionally mixing the premix with a lubricant;

(v) optionally adding additional excipients and/or adjuvants in any of steps (i) to (iv),

wherein all percentage amounts given are related to the final composition to be prepared.

(ix) EVIDENCE APPENDIX

(None)

(x) RELATED PROCEEDINGS APPENDIX

(None)